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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,822	02/08/2002	Gregory E. Hardee	ISIS-4947	4141
34138	7590	04/06/2005	EXAMINER	
COZEN O'CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508			GIBBS, TERRA C	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,822

Applicant(s)

HARDEE ET AL.

Examiner

Terra C. Gibbs

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date September 20, 2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 26, 2005 has been entered.

Claims 1-25 and 28 were previously canceled without prejudice.

Claims 26 and 27 have amended.

Claims 26 and 27 have been examined on the merits.

Response to Amendment

Applicants Amendment filed January 26, 2005 has been considered. Rejections and/or objections not reiterated from the previous office action mailed July 26, 2004 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Information Disclosure Statement

Applicants information disclosure statement filed September 20, 2004 is acknowledged. Reference BP has been considered by the Examiner, however,

reference BQ has not been considered because it is not a proper reference. The cited references issued in the European Search Report for European Patent Application No: EP 00 91 0320, dated August 10, 2004, have not been listed in the information disclosure statement filed September 20, 2004, and have therefore not been considered by the Examiner. In summary, the European Search Report itself cannot be considered because it is not a proper reference and the references referred to therein have not been considered because they have not been listed in the information disclosure statement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26 and 27 are rejected under 35 U.S.C. 102(a) as being anticipated by Dean et al. [WO 98/49348].

Claim 26 is drawn to a method of delivering an oligonucleotide across a mucosal membrane in a human, comprising a plurality of carrier particles, an oligonucleotide and capric acid. Claim 27 is dependent on claim 26 and includes all the limitations of claim 26, with the further limitation, wherein said plurality of carrier particles is administered orally.

Dean et al. disclose methods for the alimentary delivery of oligonucleotides in an animal, including a human (see Abstract and claim 27). Modification to the oligonucleotide which enhance uptake following alimentary delivery are provided. For example, claims 27 and 28 are drawn to a method for administering into the alimentary canal an oligonucleotide comprising a penetration enhancer, wherein administration into the alimentary canal is oral. It is noted that Dean et al. disclose a penetration enhancer to be capric acid (see Dean et al. at page 20, line 16).

Therefore, Dean et al. anticipate claims 26 and 27.

Response to Arguments

It is noted that in the Office Action mailed July 26, 2004 the same rejection was made of record.

In response to this rejection, Applicants argue that the disclosure of Dean et al. is too broad to be anticipatory. Applicants contend that Dean et al. disclose certain modified oligonucleotides which are formulated according to methods known in the art and such formulations may include many possible ingredients as detailed throughout the Dean application. Applicants argue that the claims have been amended to recite a specific composition and this specific combination could be only be produced by picking and choosing from the large number of possibilities taught by Dean. Applicants contend that such picking and choosing is inconsistent with anticipation. Applicants rely on *In re Schaumann*, 572 F.2d 312, 314 (C.C.P.A. 1978).

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Applicant's arguments and contentions have been fully considered, but are not found persuasive. The Dean application, at Tables 1 and 2, explicitly identifies the *in vivo* bioavailability of ICAM-1 oligonucleotides following intrajejunal administration with or without penetration enhancers. It is noted that Dean et al. disclose a penetration enhancer to be capric acid (see Dean et al. at page 20, line 16). The Dean application, at Tables 1 and 2, further discloses that oligonucleotides, along with bile salts (CDCA), were used alone or in combination with fatty acids (2% CDCA, 4% **Na caprate**, and 4% Na laurate). Therefore, the specific composition, namely an oligonucleotide and capric acid, as used in the instant claimed method, is explicitly taught by Dean et al., and not by picking and choosing from the large number of possibilities.

Claims 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Lockett et al. [WO 97/25339].

Lockett et al. disclose explicitly claims a method for introducing a nucleic acid into a cell, wherein the cell is a human, wherein the nucleic acid comprises caprate; in which the method is conducted *in vivo*; in which the nucleic acid is administered orally or by suppository (see Abstract and claims 1, 5, 10, and 11).

Therefore, Lockett et al. anticipate claims 26 and 27.

Response to Arguments

It is noted that in the Office Action mailed July 26, 2004 the same rejection was made of record.

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In response to this rejection, Applicants argue that the claims have been amended to recite a specific composition and this specific combination could be only be produced by picking and choosing from the large number of possibilities taught by Lockett et al. Applicants contend that such picking and choosing is inconsistent with anticipation.

Applicant's arguments and contentions have been fully considered, but are not found persuasive. The Lockett application, explicitly claims a method for introducing a nucleic acid into a cell using the specific composition, namely an oligonucleotide and capric acid, as used in the instant claimed method, and not by picking and choosing from the large number of possibilities (see what is explicitly claimed in claims 1, 5, 10, and 11).

Therefore, it is the Examiner's position that Lockett et al. clearly anticipate the instant claimed method.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LeGuyader John can be reached on 571-272-0760. The

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fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tcg
March 21, 2005



ANDREW WANG
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